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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,546	10/10/2003	K. M. Slimak	TPP 31413DIV	9719

7590 02/23/2007  
STEVENS, DAVIS, MILLER & MOSHER, L.L.P.  
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Washington, DC 20036

EXAMINER
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WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1655

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/682,546

Applicant(s)

SLIMAK, K. M.

Examiner

Randall Winston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-7,9-20 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,9-14 and 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submissions filed on 02/01/2007 has been entered.

Examiner has acknowledged that claims 3 and 8 have been cancelled. In Examiner's non-final office action of 11/02/2005, applicant's election with traverse of the election of species requirement of a) aroid b) seizure c) non-verbal autistic child was made final. Thus, claims 15 and 16 are withdrawn from further consideration to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Readable claims 1-2,4-7, 9-14 and 17-20, (i.e. the election of species of a) aroid b) seizure c) non-verbal autistic child), will be examined on the merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-2,4-7, 9-14 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 20 are rendered vague and indefinite for the phrases "a method comprising" and "method for treating a human comprising". The metes and bounds of the above phrases cannot be delineated by examiner. Since in claim 1 applicant has deleted the phrase "for treating chronic disease, conditions and symptoms in animals", Examiner cannot discern what the claimed method is being used for? (e.g., the claimed method is being used to treat what types of diseases or conditions or symptoms in either claim 1 or in claim 20? It appears to Examiner that Applicant claimed method is being used to treat any and/or all chronic diseases or conditions or symptoms)

Claim 2 is rendered vague and indefinite for the terms "claim 1 further" and "allergents." The above terms are misspelled. Corrections are required.

All other claims depend directly from the rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2,4-7, 9-14 and 17-20 are rejected under 35 U.S.C. 112, first paragraph.

In applicant's response on 02/01/2007, Applicant argues that Applicant provides an attached Declaration of Karen M. Sliamk, which explains that the method of the present claims can, and has been, used in the treatment of over 150 different symptoms/conditions. Applicant's argument is not found persuasive because Applicant's submitted Declaration is very unclear and incomplete. Examiner cannot discern from the Declaration of what are the claimed tropical root crops being used to treat each claimed 150 symptoms or conditions. (e.g. what are the claimed tropical root crops being used to treat abnormal pituitary function and how effective were the claimed tropical root crops in treating that claimed condition of abnormal pituitary function? Applicant has failed to provide any data and/or any guardians and/or any working examples in order for Examiner to conclude the claimed method would have a reasonable expectation of success.)

Furthermore, Claims 1-2,4-7, 9-14 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for a method of treating particular conditions and symptoms in animals, including humans (i.e. Applicant is enabled for treating the particular conditions and symptoms recited in claim 1 of Application No. 09/889,133 issued as U.S. Patent No. 6,632,461. Also please note Application 10/682,546 being a divisional of parent application 09/889,133) selected from the group consisting of autism, anxiety, arthritis, asthma, colic, congestion, diabetes, digestive upsets, irritable bowel syndrome, eczema, fatigue, migraine headaches, multiple sclerosis, seizures and rashes comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of

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tropical root crops selected from the group consisting of white sweet potato, malanga, cassava, true yam, water chestnut, arrowroot, and lotus for a period of at least five days to said patient (as recited in claim 1 of US 6,632,461), the specification does not enable any person in the art in preparing a method of treating any and/or all chronic diseases, conditions and symptoms in animals (see, e.g. above 1122<sup>nd</sup> paragraph rejection whereas claim 1 and claim 20 are claiming a method of treating any and/or all chronic conditions or symptoms), comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a method of treating any and/or all chronic diseases, conditions and symptoms in animals, comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient. Applicant has reasonably demonstrated on pages 51-54, examples III-VI of the specification, a method of treating particular conditions and symptoms in animals, including humans (i.e. those recited in claim 1 of

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Application No. 09/889,133 issued as U.S. Patent No. 6,632,461) selected from the group consisting of autism, anxiety, arthritis, asthma, colic, congestion, diabetes, digestive upsets, irritable bowel syndrome, eczema, fatigue, migraine headaches, multiple sclerosis, seizures and rashes comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of tropical root crops selected from the group consisting of white sweet potato, malanga, cassava, true yam, water chestnut, arrowroot, and lotus for a period of at least five days to said patient (as recited in claim 1 of US 6,632,461). Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method of treating any and/or all chronic diseases, conditions and symptoms in animals, comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient.

Moreover, it should be noted that the state of the prior art at the time the invention was filed did not recognize a method of treating any and/or all chronic diseases, conditions and symptoms in animals via any method including the method instantly claimed. For example, Slimak et al. et al. teach (US 5789012 see, e.g. title, column 2, lines 33-35) feeding tropical root crops selected from the group consisting of sweet potatoes, cassava, edible aroids, amaranth, yams lotus and potatoes to treat conditions such as food allergies. Thus, the art is silent regarding the efficacy of applicant's method of treating any and/or all chronic diseases, conditions and symptoms in animals, comprising a) withholding all food for at least 5 days, except for tropical root

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crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient. Therefore, applicant's claimed method is highly unpredictable in the art. In addition, the applicant's specification fails to provide guidance or working examples whereby applicant prepares a method of treating any and/or all chronic diseases, conditions and symptoms in animals, comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient.

Therefore, it would require undue experimentation without a reasonable expectation of success for one of skill in the art to practice the invention commensurate in scope with the claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER R. TATE  
PRIMARY EXAMINER